EC Certificate Production Quality Assurance System FI15/07009

The management system of

Foshan Chuangxin Medical Apparatus Co., Ltd.

Eastern Industrial Development Zone, Xiadong Chongkou Pingliu Road,
Guicheng Street, Nanhai District, Foshan City, Guandong Province,
P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex V

For the following products

Integral dental units

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 22 January 2019 until 3 December 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 3 December 2015
This certification is based on decision: FI15/07009P1

Authorised by

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd., Notified Body 0598

DECISION

22 January 2019

FI15/07009P1

Foshan Chuangxin Medical Apparatus Co.,Ltd
Eastern Industrial Development Zone,
Xiadong Chongkou Pingliu Road,
Guicheng Street, Nanhai District,
Foshan City, Guangdong Province,
P.R.China

EC-certification application 2015-08-21

Subject	Re-certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V Section 3.
Manufacturer	Foshan Chuangxin Medical Apparatus Co.,Ltd Eastern Industrial Development Zone, Xiadong Chongkou Pingliu Road, Guicheng Street, Nanhai District, Foshan City, Guangdong Province, P.R.China
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Integral dental unit	CX-2305	IIa
Integral dental unit	CX-2311	IIa
Integral dental unit	CX-8000	IIa
Integral dental unit	CX-8900	IIa
Integral dental unit	CX-9000	IIa

Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision is based on re-certification audit report(s) 281759. The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.
Certificate related to decision	FI15/07009, Issue 2
Attachment to certificate	Attachment 1, Issue 2
Valid until	This decision is valid until 3 December 2024 providing the requirements of the certification are fulfilled.
Date	Helsinki, 22 January 2019

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd, Notified Body 0598

Attachment 1 Issue 2 to SGS Fimko Ltd. EC certificate FI15/07009 Issue 2

Manufacturer	Foshan Chuangxin Medical Apparatus Co.,Ltd
Address	Eastern Industrial Development Zone, Xiadong Chongkou Pingliu Road, Guicheng Street, Nanhai District, Foshan City, Guangdong Province, P.R.China
Activity and Product Category	93/42/EEC Annex V Integral dental units

List of product names and the corresponding product type/model markings with trademarks/marketing names covered by this certificate:

Product Name	Class	Model/type nr. and Trademark(s)
Integral dental unit	IIa	CX-2305
Integral dental unit	IIa	CX-2311
Integral dental unit	IIa	CX-8000
Integral dental unit	IIa	CX-8900
Integral dental unit	IIa	CX-9000

Authorised by

Seppo Vahasalo
SGS Fimko Ltd., Notified Body 0598

Date issued/revised: 22.2.2019